

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL SEARCHING AUTHORITY

DEC 13 2005

**PCT** DUE DATE 2-9-06  
BY: AB/11/2

To:  
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

**08 NOV 2005**

Applicant's or agent's file reference

EX05-004C-PC

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/03560

27 January 2005 (27.01.2005)

28 January 2004 (28.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 33/53 and US CL: 435/2, 3, 6, 7.23, 7.24, 7.92, 7.93, 7.94, 26, 40.52, 374, 375, 287.2; 436/501, 15, 64, 164, 172,811

Applicant

EXELIXIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Date of completion of this opinion

12 October 2005 (12.10.2005)

Authorized officer

Gallene R. Gabel

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/03560

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US05/03560

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)

Claims 1-25

YES

Claims NONE

NO

Inventive step (IS)

Claims 1-25

YES

Claims NONE

NO

Industrial applicability (IA)

Claims 1-25

YES

Claims NONE

NO

**2. Citations and explanations:**

Claims 1-25 meet the criteria set out in PCT Article 33(2)-(3), because the prior art of record does not teach or fairly suggest providing inositol 1,4,5-triphosphate 3-kinase (ITPK or IP3K) as an assay system of cultured cells for contact with a test agent, wherein test agent-biased activity upon the cells is compared with a reference activity to determine the presence of modulatory effect by the test agent, and determining therefrom, if the test agent is a candidate IGFR (Insulin-like Growth Factor) pathway modulating agent. Prior art of record also fails to teach diagnosing a disease in a patient, wherein a patient sample is contacted with a probe for ITPK or IP3K polypeptide, and using quantitative measurement of ITPK or IP3K expression to diagnose a disease such as cancer.

Cooke et al. (US 2004/0265790) is relevant X,P art that teaches diagnosing a disease in a patient, wherein a patient sample is contacted with a probe for ITPK or IP3K polypeptide, and using quantitative measurement of ITPK or IP3K expression to diagnose a disease such as cancer.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability in the Diagnostic Oncology because the subject matter claimed can be made or used in industry.